PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61N 1/36

A1

(11) International Publication Number: WO 97/47357

(43) International Publication Date: 18 December 1997 (18.12.97)

(21) International Application Number: PCT/GB97/01565

(22) International Filing Date: 11 June 1997 (11.06.97)

(30) Priority Data:

9612388.0	13 June 1996 (13.06.96)	GB
9622267.4	25 October 1996 (25.10.96)	GB
9624386.0	23 November 1996 (23.11.96)	GB

(71) Applicant *(for all designated States except US)*: THE VICTORIA UNIVERSITY OF MANCHESTER [GB/GB]; Oxford Road, Manchester M13 9PL (GB).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: OLDHAM, Jacqueline, Ann [GB/GB]; 3 James Court, Liverpool L25 8TJ (GB).

(74) Agent: ALLMAN, Peter, John; Marks & Clerk, Sussex House, 83-85 Mosley Street, Manchester M2 3LG (GB).

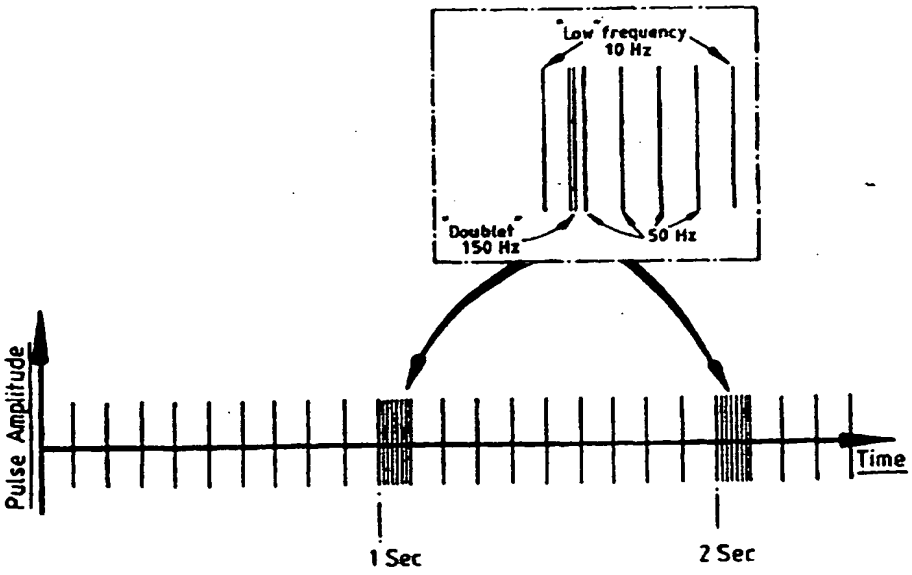
(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published

With international search report.

Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: STIMULATION OF MUSCLES



(57) Abstract

A muscle stimulator for improving muscle strength and/or endurance. Stimulating pulses are applied to the muscle, the pattern of pulses including a first component in the form of a continuous train of pulses at a first pulse repetition frequency of for example between 1 and 6Hz, a second component in the form of a series of pulse trains at a second pulse repetition frequency, for example 40 to 60Hz, and a third component in the form of a pair of pulses at a third pulse repetition frequency, for example 120 to 200Hz.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	**ES**	Spain	**LS**	Lesotho	**SI**	Slovenia
AM	Armenia	**FI**	Finland	**LT**	Lithuania	**SK**	Slovakia
AT	Austria	**FR**	France	**LU**	Luxembourg	**SN**	Senegal
AU	Australia	**GA**	Gabon	**LV**	Latvia	**SZ**	Swaziland
AZ	Azerbaijan	**GB**	United Kingdom	**MC**	Monaco	**TD**	Chad
BA	Bosnia and Herzegovina	**GE**	Georgia	**MD**	Republic of Moldova	**TG**	Togo
BB	Barbados	**GH**	Ghana	**MG**	Madagascar	**TJ**	Tajikistan
BE	Belgium	**GN**	Guinea	**MK**	The former Yugoslav Republic of Macedonia	**TM**	Turkmenistan
BF	Burkina Faso	**GR**	Greece			**TR**	Turkey
BG	Bulgaria	**HU**	Hungary	**ML**	Mali	**TT**	Trinidad and Tobago
BJ	Benin	**IE**	Ireland	**MN**	Mongolia	**UA**	Ukraine
BR	Brazil	**IL**	Israel	**MR**	Mauritania	**UG**	Uganda
BY	Belarus	**IS**	Iceland	**MW**	Malawi	**US**	United States of America
CA	Canada	**IT**	Italy	**MX**	Mexico	**UZ**	Uzbekistan
CF	Central African Republic	**JP**	Japan	**NE**	Niger	**VN**	Viet Nam
CG	Congo	**KE**	Kenya	**NL**	Netherlands	**YU**	Yugoslavia
CH	Switzerland	**KG**	Kyrgyzstan	**NO**	Norway	**ZW**	Zimbabwe
CI	Côte d'Ivoire	**KP**	Democratic People's Republic of Korea	**NZ**	New Zealand		
CM	Cameroon			**PL**	Poland		
CN	China	**KR**	Republic of Korea	**PT**	Portugal		
CU	Cuba	**KZ**	Kazakstan	**RO**	Romania		
CZ	Czech Republic	**LC**	Saint Lucia	**RU**	Russian Federation		
DE	Germany	**LI**	Liechtenstein	**SD**	Sudan		
DK	Denmark	**LK**	Sri Lanka	**SE**	Sweden		
EE	Estonia	**LR**	Liberia	**SG**	Singapore		

STIMULATION OF MUSCLES

The present invention relates to an apparatus and method for the electrical stimulation of muscle which rely upon a particular pattern of electrical stimulation.

It is well known that muscle contraction is caused by neural stimulation. Contraction occurs when an action potential is conducted down a nerve to a neuromuscular junction, the signal is then communicated to muscle cells and leads to the stimulation of the release of calcium ions into the cytoplasm of muscle cells which thereby modifies interactions between contractile proteins resulting in muscular contraction.

It has been long established that the application of an electrical field to muscles results in an artificially induced contraction of said muscles. Furthermore, as well as directly causing muscular contraction, electrical stimulation at specific frequencies can also modify the phenotype of a muscle. For instance, prolonged stimulation of a fast-twitch muscle with a uniform frequency of 10Hz results in the fast-twitch muscle developing slow-twitch characteristics, namely increased endurance, but with less power than would be normal for fast-twitch muscle. Conversely, prolonged stimulation of a slow-twitch muscle with an intermittent frequency of 30-50Hz results in the slow-twitch muscle developing fast-twitch characteristics, namely increased power, but with less endurance than would be normal for slow-twitch muscle.

It has been suggested that electrical stimulation of muscles may be a useful means of improving strength and/or endurance of incapacitated muscle (due to injury, under-use or some pathological condition). For a number of years muscles have been stimulated by Faradic stimulation delivering uniform frequencies (of around 30-50Hz) with the aim of beneficially affecting the muscle. However, these treatments have at best been ineffective and at the worst harmful to the muscle in the long term.

UK Patent GB 2 156 682 examined the electrical discharge of nerves innervating muscle with an aim of developing a means of beneficially stimulating muscle. It discloses a method of recording electrical discharges from nerves innervating muscles. A signal generated on the basis of the recording is then used to "electrotrophically" stimulate muscle. Electrotrophic stimulation is defined as "the electrical stimulation of muscle fibre using a stimulating signal containing information effective to cause structural and/or functional change of muscle fibre without requiring the muscle fibre to respond mechanically to the stimulation". However the stimulating signal of GB 2 156 682 is complex and difficult to generate.

It is an object of the present invention to provide an improved apparatus and method for electrically stimulating a muscle to improve strength and endurance of the muscle.

According to the present invention there is provided an electrical muscle stimulator including means for generating a stimulating signal comprising a first

component in the form of a train of pulses at a first pulse repetition frequency, a second component in the form of a series of pulse trains at a second pulse repetition frequency higher than the first, and a third component in the form of a pair of pulses at a third pulse repetition frequency higher than the second pulse repetition frequency, each pair of pulses being coupled with a respective train of pulses of the second component.

The invention also provides a method for electrically stimulating a muscle in which a stimulating signal is applied to the muscle, the stimulating signal including a first component in the form of a train of pulses at a first pulse repetition frequency, a second component in the form of a series of pulse trains at a second pulse repetition frequency higher than the first, and a third component in the form of a pair of pulses at a third pulse repetition frequency higher than the second pulse repetition frequency, each pair of pulses being coupled with a respective train of pulses of the second component.

It is preferred that the first pulse repetition frequency is between 1 and 15Hz, for example between 1 and 6 Hz or between 5 and 15Hz. It is also preferred that the second pulse repetition frequency is between 30 and 60Hz, for example between 40 and 60 Hz and the third pulse repetition frequency is between 120 and 300Hz, for example between 120 and 200Hz.

The inventor believes that stimulation of muscle with the electrical signal of the invention is of great benefit in the rehabilitation of, regeneration of or prevention of atrophy of skeletal muscle. Inspiration for the invention has arisen

from the examination of electrical discharge from nerves innervating muscle. It has been established that certain signals cause muscular contraction and also have unexpected beneficial effects on muscular strength and endurance.

An embodiment of the invention will now be described, by way of example, with reference to the accompanying drawing.

The attached drawing illustrates one pulse pattern generated in an electrical muscle stimulator in accordance with the invention. It will be noted that pulses are generated at regular intervals of 0.1 second such that the pulse pattern incorporates a continuous 10Hz first component. At periodic intervals this continuous relatively low frequency component is combined with short bursts of a higher frequency second component, in the illustrated case a series of four pulses at 0.2 second intervals such that the pulse repetition rate of the second components corresponds to 50Hz. In addition, a third component in the form of a "doublet" of pulses is coupled with the second component, in the illustrated case the spacing between the two pulses of the doublet is 0.0066 seconds representing a pulse repetition rate of 150Hz. It will be noted that in the illustrated case the third component immediately precedes the second component, although its position relative to the second component may differ from that shown in this example.

All of the pulses represented in the accompanying drawing are of identical structure, each pulse including positive and negative-going components. Pulse shapes such as used in conventional muscle stimulation equipment may be

used, the advantages of the invention arising from the pattern of such pulses rather than of the shape of individual pulses.

Good results have been achieved using the pattern of pulses represented in the drawing. It is believed however that a further improvement can be achieved by reducing the frequency of the low frequency component from 10Hz as shown to 6Hz or below.

It is believed that a course of treatment relying upon the described pulse pattern could be for one to three hours per day every day over a six to eight week period. The pulses could be applied to any muscle throughout the body via simple self adhesive electrodes. The pulses could be applied for "on" times of from ten to fifty seconds, with periods of inactivity, i.e. "off" times, of approximately the same duration. Good results have been obtained with "on" times of ten seconds in combination with "off" times of fifty seconds.

CLAIMS

1. An electrical muscle stimulator comprising means for generating a stimulating signal including a first component in the form of a train of pulses at a first pulse repetition frequency, a second component in the form of a series of pulse trains at a second pulse repetition frequency higher than the first, and a third component in the form of a pair of pulses at a third pulse repetition frequency higher than the second pulse repetition frequency, each pair of pulses being coupled with a respective train of pulses of the second component.

2. An electrical muscle stimulator according to claim 1, wherein the first pulse repetition frequency is between 1Hz and 15Hz.

3. An electrical muscle stimulator according to claim 2, wherein the first pulse repetition frequency is between 1 and 6Hz.

4. An electrical muscle stimulator according to claim 2, wherein the first pulse repetition frequency is between 5 and 15Hz.

5. An electrical muscle stimulator according to any preceding claim, wherein the second pulse repetition frequency is between 30 and 60Hz.

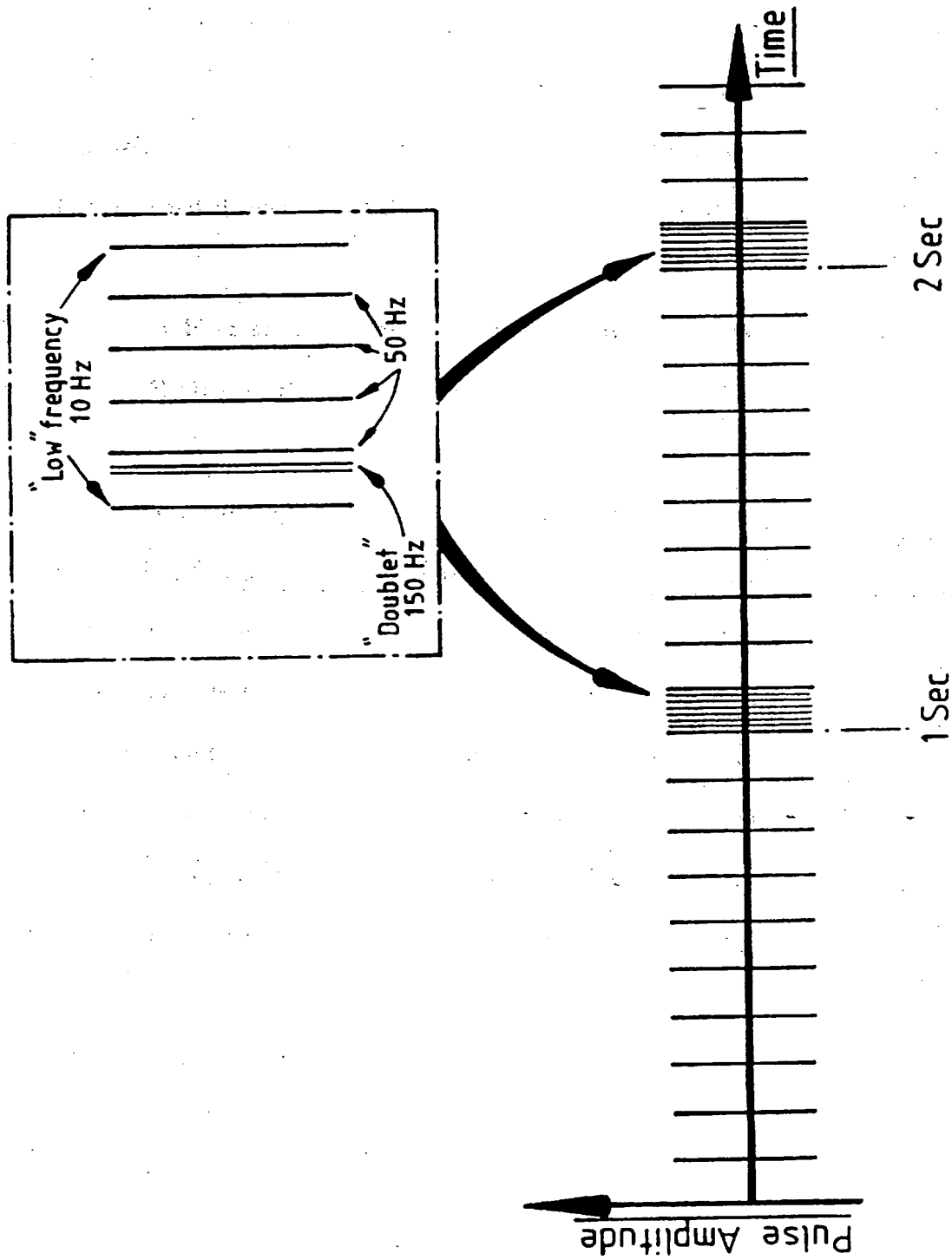
6. An electrical muscle stimulator according to claim 5, wherein the second pulse repetition frequency is between 40 and 60Hz.

7. An electrical muscle stimulator according to any preceding claim, wherein the third pulse repetition frequency is between 120 and 300Hz.

8. An electrical muscle stimulator according to claim 7, wherein the third pulse repetition frequency is between 120 and 200Hz

9. A method for electrically stimulating a muscle in which a stimulating signal is applied to the muscle, the stimulating signal including a first component in the form of a train of pulses at a first pulse repetition frequency, a second component in the form of a series of pulse trains at a second pulse repetition frequency higher than the first, and a third component in the form of a pair of pulses at a third pulse repetition higher than the second pulse repetition frequency, each pair of pulses being coupled with a respective train of pulses of the second component.

10. An electrical muscle stimulator substantially as herein before described.


Time
2 Sec
1 Sec
"Low" frequency 10 Hz
50 Hz
"Doublet" 150 Hz
Pulse Amplitude

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 97/01565

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61N1/36

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 097 833 A (CAMPOS) 24 March 1992 see the whole document	1-10
A	US 4 177 819 A (KOFSKY & AL.) 11 December 1979 see column 1, line 35 - column 2, line 31	1-10

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
25 September 1997	13. 10. 97

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016	Lemercier, D

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/GB 97/01565

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5097833 A	24-03-92	NONE	
US 4177819 A	11-12-79	NONE	